

## **DISPOSITION OF STAFF REQUIREMENTS MEMORANDUM (SRM) ISSUES**

In response to SECY-98-185, the Commission issued a Staff Requirements Memorandum (SRM), dated December 1, 1998, that directed the staff to obtain stakeholder input and revise the draft proposed 10 CFR Part 70 rule revisions while considering the input received, and according to Commission direction. In that SRM, the Commission directed the staff to: (1) decide what is fundamental, for NRC's regulatory purposes, for inclusion as part of the license or docket, and what can be justified from a public health and safety and cost-benefit basis, and assure that Part 70 captures, for submittal, those few significant changes that currently would require license amendments; (2) require licensees/applicants to address baseline design criteria and develop a preliminary integrated safety analysis (ISA) for new processes and new facilities; (3) justify, on a health and safety or cost-benefit basis, any requirement to conduct a decommissioning ISA; (4) require that any new backfit pass a cost-benefit test, without the "substantial" increase-in-safety test; (5) require the reporting of certain significant events because of their potential to impact worker or public health and safety; (6) clarify the basis for use of chemical safety and chemical consequence criteria, particularly within the context of the Memoranda of Understanding with the Occupational Safety and Health Administration and other Government agencies; (7) critically review the Standard Review Plan (SRP) to ensure that by providing specific acceptance criteria, it does not inadvertently prevent licensees or applicants from suggesting alternate means of demonstrating compliance with the rule; and (8) request input on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities.

The following discussion describes how the staff incorporated the Commission direction.

### **Issue 1(a): ISA Summary in the License**

#### **A. Contents of SECY-98-185**

In SECY-98-185 the staff proposed that the results or summary of the ISA be submitted along with the license application and that this information would be considered part of the license. This was stated in 10 CFR 70.65, which addressed the additional information that is required to be submitted with the license application, to comply with the new proposed subpart. One of the reasons for including the ISA summary as part of the license was to control, and to keep NRC informed of, future changes to the document.

#### **B. Commission Direction in SRM to SECY-98-185**

The Commission, in an SRM to SECY-98-185, directed the staff as follows:

"The Commission agrees that Part 70 should require licensees to perform, document, maintain, and update an Integrated Safety Analysis (ISA)." "The Commission was not persuaded that it is necessary for the results of the ISA to be included in the license and is concerned that such a requirement would bring with it the need for what appears to be an

unworkable 10CFR 50.59-like change process.

### **C. Comments received during public interaction on draft rule language**

During the December 3-4, 1998 public meeting, the Nuclear Energy Institute (NEI) stated its continued concern that placing the ISA summary in the license would create numerous and unnecessary license amendments. In a follow-up letter dated December 22, 1998, NEI stated that it concurred with the Commission that licensees should be required to perform, document, maintain, and update an ISA; however NEI does not believe the ISA summary should be in the license. It stated:

"This requirement would create an unnecessary administrative burden in managing commercially sensitive documents, would drastically increase the number of requests for license amendments(via a 10 CFR 50.59-like change process), would require appreciable administrative support and would force both the NRC and licensee to allocate significant resources away from safety at the facilities."

### **D. Staff response to SRM and disposition of comments**

In response to these concerns the staff has removed the requirement for the ISA summary to be included as part of the license. The summary is required to be submitted in conjunction with the license application but will be maintained on the docket. Since the document is not contained in the license, an amendment is not required before a change for those changes that are permitted by 10 CFR 70.72(c).

## **Issue 1(b): 10 CFR 70.72 Change Process**

### **A. Contents of SECY-98-185**

In SECY-98-185 the staff proposed a modified 10 CFR 50.59-type change process. Section 70.72 stated

A licensee may make changes to site, structures, systems, equipment, components, and activities of personnel, without prior Commission approval, if the change-

- 1) Results in, at most, a minimal increase in the likelihood or consequences of an accident previously evaluated in the ISA;
- 2) Would not create a potential for an accident different from any previously evaluated in the ISA; and
- 3) Is not inconsistent with NRC requirements and license conditions.

### **B. Commission Direction in SRM to SECY-98-185**

The Commission, in an SRM to SECY-98-185, directed the staff as follows:

"With regard to changes to the ISA or safety program, Part 70 does need to capture for submittal those few significant changes that currently would require license amendments. The staff should decide what is fundamental for NRC's regulatory purposes for inclusion as part of a license or docket and what can be justified from a public health and safety and cost-benefit basis."

### **C. Comments received during public interaction on draft rule language**

NEI has commented that the proposed change process in SECY-98-185 would require too many amendments and would require NRC pre-approval for small changes that industry is currently allowed to make without pre-approval.

In a letter dated January 26, 1999, NEI stated that the change mechanism should be structured "...to limit the number of change (and license amendment) requests to the NRC to those that are risk-significant..." and "...(it) should be risk-informed and be consistent with current practices in the regulation of fuel cycle facilities."

In addition, NEI also stated in that letter:

"NEI is concerned, however, that the proposed 70.72 change mechanism may prove difficult to implement. The inherently qualitative nature of the ISA used to establish whether or not NRC pre-approval is needed for a change makes assessment of what constitutes '...a minimal increase...' a highly subjective call".

### **D. Staff response to SRM and disposition of comments**

In response to these concerns the staff has revised the change process as reflected in Section 70.72. The staff reviewed all license amendment requests that NRC has received for Part 70 licensees over the past 3 years. In addition, the Task Force determined that only substantial changes to the facilities required license amendments in the past for fuel cycle licensees, such

as the creation and use of a new process at a facility (i.e., downblending, or increased enrichment). This section was then revised to place the threshold for pre-approval of changes at a level consistent with past practice. In addition the subjective “more than minimal” words were removed and specific situations where pre-approval would be required were added. This section was also modified to tie-back to the information submitted as part of the ISA summary. This helps remove the subjective nature of the determination of pre-approval, and made it clear which information should be considered when making this determination.

## **Issue 2(a): Baseline Design Criteria (BDC)**

### **A. Contents of SECY-98-185**

In SECY-98-185, 10 CFR 70.64, the staff proposed that a set of 10 BDC be applied to new facilities and to new processes at existing facilities. These BDC represent design principles that were to be applied from the outset of the design activity (i.e., before obtaining risk information through the performance of the ISA or preliminary ISA). The draft statement of considerations for SECY-98-185 explained the purpose of the BDC requirements:

. . . for new processes and facilities, the Commission recognizes that good engineering practice dictates that certain minimum requirements be applied as design and safety considerations for any new nuclear process or facility. Therefore, the Commission has specified baseline design criteria in 10 CFR 70.64 that are similar to the general design criteria in Part 50, Appendix A; Part 72, Subpart F; and 10 CFR 60.131. The baseline design criteria identify 10 initial safety design considerations, including: quality standards and records; natural phenomena hazards; fire protection; environmental and dynamic effects; chemical protection; emergency capability; utility services; inspection, testing, and maintenance; criticality control; and instrumentation and controls. The baseline design criteria do not provide relief from compliance with the safety performance requirements of [then] 10 CFR 70.60. The baseline design criteria are generally an acceptable set of initial design safety considerations, which may not be sufficient to assure adequate safety for all new processes and facilities. The ISA process is intended to identify additional safety features that may be needed. On the other hand, the Commission recognizes that there may be processes or facilities for which some of the baseline design criteria may not be necessary or appropriate, based on the results of the updated ISA. For such processes and facilities, any design features that are inconsistent with the baseline design criteria should be identified and justified.

### **B. Commission Direction in SRM to SECY-98-185**

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

“Part 70 should also require licensees/ applicants to address baseline design criteria . . . for new processes and new facilities.”

### **C. Comments received during public interaction on draft rule language**

NEI provided two separate written comments on this issue during the period of public interaction on the staff's draft requirements. NEI's second set of comments was a change in position from the first. In addition, one existing Part 70 licensee submitted comments in this area through the World Wide Web discussion forum. Each of the comments is described below.

In a January 26, 1999, letter, NEI commented on the BDC requirement in SECY-98-185:

". . . the December 1, 1998 Staff Requirements Memorandum (SRM) for

SECY-98-185 supports the need for a license applicant to *address* baseline criteria in the design of a new facility or process. NEI recommends that this requirement remain in the proposed Part 70 revisions, but that it not apply to existing licensees."

The basis provided for this recommendation and the added emphasis on the word *address* was given by NEI as:

. . . a properly executed ISA will have already addressed baseline design criteria and other factors to protect against undesirable consequences in a risk-informed manner. There is, therefore, no need for a current licensee to address or adhere to the baseline design criteria of §70.74 [sic; §70.64 intended]. The license commitment to perform, implement, update, and maintain an ISA is a broad licensing basis which encompasses, by reference, stringent baseline design criteria. NEI further believes that changes to an existing facility (e.g., process technology) should not be subject to the §70.64 baseline design criteria.

In a second set of written comments provided March 26, 1999, NEI commented on the staff's revised rule language that was posted on the World Wide Web on March 1, 1999. These NEI recommendations represented changes in position from the earlier NEI comments. NEI no longer objected to the application of BDC to existing licensees, subject to limitation and clarification:

The baseline design criteria (BDC) should be clarified to state that BDC should not be backfitted onto existing facilities or processes, even if the new process is housed in an existing building or is adjacent to an existing process. Unless a licensee proposes a change that lies outside a facility's licensing basis, the licensee should not be subject to the provisions of §70.64. For new processes at existing facilities NEI has modified §70.64 to state that the BDC would only apply if implementation of the new process would require a license amendment under §70.72.

NEI provided suggested rewording for 10 CFR 70.64(a) and also for 10 CFR 70.64(b), regarding a design preference for the selection of engineered controls over administrative controls. NEI also: (1) recommended deletion of the definition "new process at existing facility"; (2) commented that the regulation should not mandate that licensees identify a "defense-in-depth" strategy or incorporate "defense-in-depth" design principles for new facilities and new processes at existing facilities; and (3) recommended that the BDC on instrumentation and controls should be incorporated into the BDC for inspection, testing, and maintenance (under a new name, "monitoring, inspection, testing, and maintenance"). NEI stated that "defense-in-depth" was appropriate for inclusion as guidance, but was not appropriate for rule language.

The only other comment related to BDC was submitted by a Part 70 licensee on the World Wide Web site discussion forum. The comment took issue with the draft definition posted by the staff -- New Processes at Existing Facilities -- stating that one reasonable interpretation of the definition would result in many more changes requiring application of BDC, and NRC preapproval of the new process, than the staff likely intended.

#### **D. Staff response to SRM and disposition of comments**

The new rule language continues to apply BDC to new facilities and new processes at existing facilities. The staff believes that the clarifications that have been made to the draft rule text related to BDC are consistent with the Commission's direction provided in the SRM and will partially address NEI's and industry's concerns in this area. An exception is that, contrary to the NEI comment, the rule continues to require that the design process incorporate defense-in-depth practices in the design of new facilities and processes.

The staff generally agrees with the approach recommended in NEI's comments submitted on March 26, 1999. In summary, NEI's suggested approach requires application of the BDC to new processes at existing facilities if the new processes would require a license amendment under the 10 CFR 70.72 (i.e., "\$50.59-like") facility change process -- changes under 10 CFR 70.72 that are not new processes (e.g., component-level changes) would not be subject to the BDC. The staff agrees with an NEI comment that the definition of "new processes at existing facilities" is unnecessary in 10 CFR 70.4, because the term is adequately described in section 10 CFR 70.64. The staff did not agree with NEI's previous recommendation to, in effect, only apply BDC to new licensees.

The staff believes the BDC are consistent with risk-informed regulation, in that, for new processes or new facilities, NRC would recognize that, because of factors such as limited operating experience, good engineering practice dictates that certain minimum requirements be applied as design and safety principles, generally independent of the risk-informed information that will be ultimately obtained and incorporated through the ISA. Note that the draft rule would allow for later incorporation of risk information, obtained through the ISA, that suggests that some BDC do not apply, or that alternative or additional BDC are appropriate for the specific process being analyzed.

The staff has clarified the BDC rule language in response to NEI's concern that application of BDC to "new processes" should not result in the need for retrofits to existing facilities/processes, even if the new process is housed in an existing building or is adjacent to an existing process. The staff agrees that the BDC are intended to apply only to the new process or new facility, and should not be construed to require retrofitting of existing facilities. However, every process or facility would need to comply with the performance requirements of 10 CFR 70.61.

The staff does not agree with NEI's recommendation to delete the requirements that, for newly-designed facilities and processes, "facility and system design and plant layout must be based on defense-in-depth practices." To clarify this issue, the staff added a footnote to section 10 CFR 70.64(b) that discusses the relevance and use of the term "defense-in-depth." The staff agrees with NEI's comments regarding preference of engineered controls over administrative controls (to increase reliability). Words similar to those proposed by NEI were incorporated, in lieu of the SECY-98-185 language, which expressed preference for "passive systems" over "active systems." This language also helps clarify the meaning of "defense-in-depth."

The staff also does not agree with NEI's recommendation to delete BDC number 10, "Instrumentation and Control Systems." NEI's comments of March 26 stated that this BDC should be incorporated into the BDC for "Inspection, Testing, and Maintenance" (under a new name, "Monitoring, Inspection, Testing, and Maintenance"). The staff prefers a separate BDC for instrumentation and control systems, to be consistent with other Commission regulations

(e.g., 10 CFR 60.131), and because the term “monitoring” as used in the NEI-suggested changes connotes “instrumentation,” but not necessarily “controls.”

## **Issue 2b: Preliminary ISA**

### **A. Contents of SECY-98-185**

In SECY-98-185, 10 CFR 70.62(a)(3) of the staff's proposed language required each applicant for a new facility or new process at an existing facility to perform a preliminary ISA and submit the results to NRC before construction of the facility or process. The preliminary ISA was to be submitted, but NRC approval was not required. The preliminary ISA would include facility and process description and design information that demonstrates the applicant's incorporation of criticality monitoring and alarm requirements in 10 CFR 70.24, the BDCs in 10 CFR 70.64, and the performance requirements. The preliminary ISA would also describe any proposed relaxation in the application of the BDC. The statement of considerations explained the preliminary ISA requirements:

Based on [the new process' or new facility's] initial designs, the applicants are expected to perform preliminary ISAs before construction of facilities. If the ISA results show deficiencies in the design, the design should be modified to assure that the items and measures planned to protect against identified accidents are adequate. On the other hand, if the ISA results show that a given item at a given facility is not relied on for safety, or that it does not require full adherence to the baseline criteria, then the facility design may be modified accordingly. The applicant is expected to submit the results of the preliminary ISA, based on the modified design of the facility, to NRC before construction. However, NRC approval is not necessary for the applicant to proceed with construction. The submittal should include the identification of all cases where a deviation from the baseline criteria is proposed, along with a justification for that decision. The submittal of the preliminary ISA for review by NRC provides an opportunity for applicants to get early feedback on the design of their facilities or processes. It is much more cost-effective to correct problems identified at the design stage than after the facility has been constructed.

### **B. Commission Direction in SRM to SECY-98-185**

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

"Part 70 should also require licensees/ applicants to . . . develop preliminary ISA for new processes and new facilities."

### **C. Comments received during public interaction on draft rule language**

NEI provided two separate written comments on preliminary ISA during the period of public interaction on the staff's draft requirements. NEI's second set of comments was a change in position from the first. In addition, one existing Part 70 licensee submitted comments in this area through the World Wide Web discussion forum. Each of the comments is described below.

At first, in a December 22, 1998, letter, NEI expressed support of performance and submittal (for NRC review, but not approval) of the preliminary ISA. NEI noted that the preliminary ISA is a concept that is consistent with industry's current practice and the concepts supported by the

American Institute of Chemical Engineering (AIChE), under the name "Process Hazards Analysis (PHA)." Therefore, NEI recommended a change to the term, *preliminary process hazards analysis* (PHA) throughout the proposed Part 70 revisions and suggested a definition of preliminary PHA be included in Section 70.4 of the rule. NEI remarked:

A license applicant would submit a preliminary PHA to the NRC at the conceptual engineering phase of the project. NRC could use the preliminary PHA for informational purposes, acknowledging that the process or facility design may undergo several refinements and redesigns prior to its eventual construction and commissioning. Based on the results of the submitted, preliminary PHA, the NRC would communicate to the applicant any concerns (e.g. over the proposed design or engineering methodology, inadequate compliance with current baseline design criteria, etc.) and recommendations for improvement.

In a second written comment provided March 26, 1999, NEI commented on the staff's revised rule language that was posted on the World Wide Web on March 1, 1999. This version of the draft rule clarified the function (which remained consistent with that in SECY-98-185) of the preliminary PHA and its relationship to the ISA. The new NEI recommendation was for deletion of the definition *preliminary process hazard analysis*, and a change in terminology from *preliminary process hazard analysis* to *preliminary process hazard evaluation*. NEI further recommended that submittal of the *preliminary process hazard analysis* to NRC not be required:

The requirement to prepare a preliminary process hazards evaluation (§70.64(c)) for new facilities or processes appears open-ended. The Rule specifies neither how the preliminary process hazards evaluation is to be used in the licensing process nor what response the NRC is to provide to the license applicant upon receipt and review of the submitted information. Applicants for Part 70 licenses have traditionally discussed proposed projects or facility changes with the NRC. The NRC has always supported this prudent and open exchange of information and industry will continue this approach in the future. NEI does not see a need to codify in Part 70 the requirement to submit a preliminary process hazards evaluation, especially when no approval of this analysis is required or formal feedback from the NRC is mandated. NEI recommends, therefore, that paragraphs (4) and (5) of draft §70.74 [sic; §70.64 is the intended reference] be deleted. [note: 10 CFR 70.64(c)(4)-(5) in SECY-98-185 concerned submittal of the preliminary ISA to NRC and noted that its NRC approval was not required].

The only other comment related to preliminary ISA was submitted by a Part 70 licensee on the World Wide Web site discussion forum. The comment was that although performance of a preliminary process hazards analysis appears to be a reasonable requirement, providing it to NRC before construction is an exercise that appears to have no function in the licensing process, and forcing early and sufficient pre-licensing communication through regulation is inappropriate.

#### **D. Staff response to SRM and disposition of comments**

In the staff's proposed rule language, any requirements regarding the preliminary PHA (or preliminary ISA) have been removed. The staff reviewed the existing provisions in Part 70 to see how they relate to the new revisions that will be added to Part 70 Subpart H. Relevant existing provisions are in 10 CFR 70.21(f) and 70.23(c)(2). Section 70.21(f) requires:

An application for a license to possess and use special nuclear material for processing and fuel fabrication, scrap recovery, or conversion of uranium hexafluoride, or for the conduct of any other activity which the Commission has determined pursuant to subpart A of part 51 of this chapter will significantly affect the quality of the environment shall be filed at least 9 months prior to commencement of construction of the plant or facility in which the activity will be conducted, and shall be accompanied by an Environmental Report required under subpart A of part 51 of this chapter.

Similarly, 10 CFR 70.23(a)(7), and (by reference) 10 CFR Part 51, require that:

Where the proposed activity is processing and fuel fabrication, scrap recovery, conversion of uranium hexafluoride, uranium enrichment facility construction and operation, or any other activity which the Commission determines will significantly affect the quality of the environment, the Director of Nuclear Material Safety and Safeguards or his designee, before commencement of construction of the plant or facility in which the activity will be conducted, on the basis of information filed and evaluations made pursuant to subpart A of part 51 of this chapter, has concluded, after weighing the environmental, economic, technical, and other benefits against environmental costs and considering available alternatives, that the action called for is the issuance of the proposed license, with any appropriate conditions to protect environmental values. Commencement of construction prior to this conclusion is grounds for denial to possess and use special nuclear material in the plant or facility. As used in this paragraph, the term 'commencement of construction' means any clearing of land, excavation, or other substantial action that would adversely affect the environment of a site. The term does not mean site exploration, roads necessary for site exploration, borings to determine foundation conditions, or other preconstruction monitoring or testing to establish background information related to the suitability of the site or the protection of environmental values.

These two provisions capture many facilities for which the BDC and preliminary ISA requirements were intended; however, the provisions may not apply to certain new processes at existing facilities. The staff believes that for new facilities (i.e., new constructions), the license application and ISA Summary will be submitted pursuant to 10 CFR 70.65 before construction begins. Note that one of the primary purposes of the preliminary ISA, as stated in SECY-98-185, was that it "... provides an opportunity for applicants to get early feedback [from NRC] on the design of their facilities or processes. It is much more cost-effective to correct problems identified at the design stage than after the facility has been constructed." Because the ISA (the complete hazard analysis) will be completed and the ISA summary submitted before construction, NRC will have an opportunity to comment on the design adequacy before construction begins.

In general, the staff agrees with the approach recommended in NEI's comments submitted on March 26, 1999. However, the staff further believes that, absent a submittal, it is unnecessary to require performance of the preliminary PHA in the Part 70 licensing regulations. The staff believes that the preliminary ISA could be a valuable pre-licensing tool, but absent submittal or approval by NRC, the staff agrees with the comment submitted on the Website that the preliminary ISA does not perform a function in the licensing process.

The staff agrees with NEI that past pre-licensing communications between NRC and prospective applicants for new licenses or new processes have been adequate. A regulatory requirement to formalize this communication is, therefore, not necessary at this time. Although the staff encourages performance of the preliminary PHA because it should provide valuable information about the safety of the facility design; the decision to perform it and use it in pre-licensing communications with NRC (for example, to avoid later facility retrofits to satisfy NRC licensing requirements) is largely a business decision that the staff recommends be left to the applicant. If this is done, staff recommends that it be done early in the process (i.e., at the 30 percent conceptual design stage).

### **Issue 3: Decommissioning ISA**

#### **A. Contents of SECY-98-185**

In SECY-98-185, the staff proposed the following requirement as 10 CFR 70.62(b):

“If the decommissioning of a facility involves potentially hazardous activities such as chemical treatment of wastes, each licensee shall perform an ISA of the decommissioning process, correct any unacceptable vulnerabilities identified in the ISA, and submit the results to NRC for approval before beginning such decommissioning activities.”

#### **B. Commission Direction in SRM to SECY-98-185**

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

“The Commission may support the proposed requirement for the conduct of a decommissioning ISA if it can be justified on a health and safety or cost-benefit basis. However, the Commission is concerned that this requirement appears somewhat redundant with that required by NRC's 1997 decommissioning rule (Part 20) that applies to Part 70 as well as other licensees.”

#### **C. Comments received during public interaction on draft rule language**

One comment was received on this issue during the period of public interaction on the staff's draft requirements. The NEI, in a December 22, 1998, letter, commented:

NEI believes that a separate decommissioning ISA is not warranted. Decommissioning should be viewed as simply one, albeit the last, phase of operation of a licensed facility. As such, the facility's existing ISA program can be used to assess the potential hazards of activities and procedures proposed for use in the decommissioning phase. Any required changes to the ISA and facility operations to protect the health and safety of workers and the public during decommissioning can be implemented within the framework of the existing ISA program. The ISA would be updated, as required, and changes to the ISA summary would be submitted to the NRC as currently practiced. There is, therefore, no need for a separate decommissioning ISA in the Part 70 rule.

The decommissioning plan submitted to the NRC in accordance with the schedule and requirements of §70.38(g) will include an ISA evaluation of the hazards posed by activities or procedures proposed for use in the decommissioning and recommendations for implementation of items relied on for safety and assurances to be placed on such controls.

The example cited in the draft language for §70.62(b)-- "...potentially hazardous activities such as chemical treatment of wastes..." -- may be inappropriate as the NRC-OSHA MOU does not grant NRC jurisdiction over management of purely chemical wastes.

NEI recommends that §70.62(b) be deleted from the proposed Part 70 revisions.

#### **D. Staff response to SRM and disposition of comments**

In accordance with the SRM direction, the staff reviewed the requirements for decommissioning in Part 20 as well as the existing requirements for decommissioning in 10 CFR 70.25 and 70.38. In addition, the staff considered the comments provided by NEI.

The staff did not identify redundancy of the ISA provisions with the decommissioning requirements of Part 20. However, the staff notes that 10 CFR 70.38(g)(4)(iii) requires that the decommissioning plan (DP) include, “. . . a description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.” Because the DP is submitted for NRC approval before initiation of “procedures and activities necessary to carry out decommissioning of the site or separate building or outdoor area,” the staff believes that there is a measure of redundancy between 10 CFR 70.38 and the draft requirements in SECY-98-185 regarding submittal of decommissioning ISA results.

The staff agrees with NEI that the facility's existing ISA program can be used to assess the potential hazards of activities and procedures proposed for use in the decommissioning phase. In this respect, the ISA should provide valuable information with respect to developing the DP's “. . . description of methods used to ensure protection of workers and the environment against radiation hazards during decommissioning.” The DP will be the vehicle for regulatory approval of the licensee's practices for protection of health and safety during decommissioning. Although the staff encourages the use of the ISA to aid in development of the DP, the staff believes that an explicit regulatory requirement to use the ISA in this manner is not warranted. Changes to 10 CFR 70.38 have not been considered in this rulemaking.

In the attached proposed Part 70 rule language, the requirements to perform an ISA with regards to decommissioning, and submit the results to NRC, have been deleted. The focus of Subpart H is limited to protection from accidents that are of sufficient credibility and consequence such that controls preventing or mitigating them have to be considered during operations. The staff believes that activities related to decommissioning are adequately regulated by existing requirements in Part 20 and 10 CFR 70.25 and 70.38. The applicability section -- §70.60 -- has been modified to indicate that requirements for decommissioning are addressed by those provisions. The addition of this sentence eliminates any potential redundancy in the regulations regarding decommissioning. Finally, because the staff's recommendation is to delete the requirement, the staff has not attempted to justify performance of a decommissioning ISA on a cost-benefit or health and safety basis.

#### **Issue 4: Backfit**

##### **A. Contents of SECY 98-185**

As part of its petition for rulemaking, NEI requested an immediately effective backfit for 10 CFR Part 70. In SECY 98-185, the staff recommended that the Commission defer a decision on backfit until after the safety basis, including the results of the Integrated Safety Analysis (ISA), are incorporated in the license, and the staff has gained sufficient experience with the ISA requirements. After completing the initial ISA, and the staff has gained experience with the ISA requirements, a baseline determination of risk could be established, as needed for a backfit analysis. This approach was initially approved by the Commission in their Staff Requirements Memorandum (SRM) dated August 22, 1997, in response to SECY 97-137.

##### **B. Commission Direction in staff requirements memorandum (SRM) to SECY 98-185**

The Commission, in the SRM to SECY 98-185, directed the staff as follows:

“The Commission supports a requirement that any new backfit pass a cost-benefit test, without the ‘substantial’ increase in safety test. The Commission believes that modest increases in safety at minimal or inconsequential cost could be justified on a cost benefit basis.”

##### **C. Comments received during public interaction on draft rule language**

In NEI’s 1997 Petition for Rulemaking, NEI requested that the Commission include a backfit provision in the revisions to 10 CFR Part 70. The Petition for Rulemaking outlined the need for the backfit to be immediately effective and that, in order for the backfit to be implemented, it must substantially increase overall protection of the public health and safety and its cost must be justified by the increased protection it affords.

In a July 7, 1998 document, “Nuclear Energy Institute White Paper on Part 70 Regulation,” provided to staff, NEI explained its basis for requesting that a backfit provision be made “immediately effective.” In its paper, NEI stated that “it is critical that the backfit provision apply immediately upon the effective date of the rule change.” NEI argues that the staff’s basis for deferring a backfit regulation in SECY-97-137 (i.e., licensee’s do not have a “well-defined” licensing bases) was faulty. NEI believes that NRC possesses an ample basis to have licensed the Part 70 facilities in the past and to have permitted their continued operation. NEI stated that the NRC staff should be able to determine whether a proposed new requirement would “substantially increase” protection of the public health or safety or common defense and security, and whether the costs of such new requirements are justified. NEI also stated that if a licensee concludes that plant or program modification are needed based on the results of the ISA, the licensee will make those changes and no backfit issue arises; however, if the staff believes additional changes are necessary, those changes should be considered under the backfit rule. NEI does caveat these statements by adding that backfit analysis is “not required” if the staff concludes that the changes are required to implement applicable requirements, however, “this is very different from the staff’s position that the backfit rule itself should not apply to plant changes based on the initial ISA’s.” This seems to indicate that although the ISA will be performed to comply with NRC regulations, if the licensee disagrees with any changes that the staff believes are necessary, as a result of the ISA, to comply with the regulations, then those changes would be subject to backfit. NEI completes its discussion regarding immediately effective backfit by addressing the delayed implementation of backfit in 10 CFR Part 76, for

which it states a number of costly plant, program, and procedural changes were required by the staff without performing a rigorous backfit analysis. NEI asserts that if a backfit analysis had been performed, a number of the modifications may have been found to be unnecessary. Finally, concerning the staff's proposal to use a qualitative backfit, NEI states that this is not consistent with NUREG/BR-0058 Rev. 2 "Regulatory Analysis Guidance of the U.S. Nuclear Regulatory Commission" which makes it clear that quantitative analyses are much preferred over qualitative ones even if the values and impacts can not be expressed in "monetary terms." NEI states that "the Commission should specify that backfit analyses performed under Part 70 will use quantitative analyses to the maximum extent possible."

By letter dated February, 12, 1999, NEI reiterated their concerns on backfit as a result of NRC staff's discussion of backfit in SECY-98-185. The concerns were the same as those in the White Paper and supported through reference to the White Paper.

#### **D. Staff response to SRM and disposition of comments**

The staff continues to believe that backfit should not be considered until after experience is gained in implementing the revised rule and until a well documented safety basis is established. At that time, if a backfit requirement were to be implemented, it would be consistent with the SECY-98-185 SRM direction and not require a "substantial" increase in safety test, i.e., modest increases in safety at a minimal or inconsequential cost would be permissible under backfit.

Backfit, as defined in §50.109(a)(1), is "the modification of or addition to systems, structures, components or design of a facility; or the procedures or organization required to design construct or operate a facility; any of which may result from a new or amended provision in the Commission rules or the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previous NRC staff position." A similar definition for backfit is found in 10 CFR Part 76. 10 CFR Part 72 is also similar, however, it does not limit backfit to new or amended Commission rules or a new or different interpretation of a staff position.

In its July 7, 1998, backfit white paper, NEI argues for the implementation of a quantitative backfit analysis versus the staff's intent to use a qualitative backfit analysis, if a backfit requirement were to be implemented. NEI argues that the use of a quantitative backfit analysis is consistent with NUREG/BR-0058 Rev. 2 which states quantitative analysis is much preferred over qualitative ones even if the values and impacts cannot be expressed in "monetary terms." The staff believes that a quantitative determination of incremental risk may require a Probabilistic Risk Assessment, to which the industry has strongly opposed in the past. Furthermore, it is not clear how a determination of incremental risk, as needed for backfit analysis, would be accomplished without an already determined baseline for the determination of risk. Currently, if backfit provisions were to be implemented, the staff intends to use the newly required ISAs to help develop the baseline; but without some level of PRA in the ISA, for which historical data may not be sufficient for these facilities, it would be difficult to quantify any backfit analysis.

NEI's interpretation of backfit also appears to be in conflict with the staff's. Although both parties agree that, if backfit were to be implemented, it would apply to changes in the regulations or interpretations of those regulations, there does seem to be some difference in opinion as to when backfit would apply to interpretations of the ISA results. Although NEI agrees that backfit would not apply to implementation of the regulations, the general nature of

Part 70 will inevitably lead to differences of opinion about whether an action is necessary to implement the regulations. For example, NEI states that if the licensee concludes that plant or program modification are needed, it will make those changes and no backfit issue arises, but if the staff believes additional changes are necessary, the staff should be required to consider such changes under the backfit rule. NRC staff believes that if, in its judgement, additional modifications are necessary to satisfy the performance requirements of the rule, it is a issue related to implementing the regulations, and that NRC should be responsible for interpreting the implementation of the regulations, not the licensee. In the past, differences of opinion related to implementation of the regulations have usually been successfully resolved through discussion at the staff level after the licensee has identified and justified their concern that an NRC request may be beyond what is required by the regulations. If the differences cannot be resolved at the staff level, as in the past, it will be elevated to higher levels of NRC and licensee management for resolution. If backfit is developed in Part 70 similar to the requirements in §50.109(a)(4)(i), the burden to show that an issue is related to implementing the regulations is placed upon the staff and thus the staff's implementation of Part 70 could result in the need for significantly larger resources if licensees attempt to argue regulatory interpretations based on the generality of the regulations in Part 70.

The current basis for licensing a Part 70 facility is the general regulations in 10 CFR Part 70, the licensee's application, and license conditions. Although the staff believes existing, operating facilities to be safe, there is not sufficient confidence in the margin of safety because of the absence of a well-defined, risk-informed safety basis. The staff has developed proposed revisions to 10 CFR Part 70 which require development of an ISA. The staff believes, and industry appears to agree, that development of an ISA would help define a risk-informed safety basis; however, industry believes that the current safety basis is sufficient to implement backfit. Staff view is that the current safety basis would not correspond to the performance requirements of the rule. In addition, staff believes that experience with ISAs, developed using the performance requirements of the rule, is necessary to ensure that the ISAs are sufficient to provide the appropriate safety basis. Therefore, the staff believes that backfit should be deferred until the safety basis corresponding to the revised rule is established.

Deferring backfit is also consistent with staff's implementation of Part 76 regulations where backfit was delayed until after certification was completed. The commitments in the Gaseous Diffusion Plant Compliance Plans were never subject to the backfit provision. Although NEI argues that a number of the modifications for GDPs may have been found to be unnecessary if backfit were applied, the staff required most of these modifications to bring the GDPs into compliance with existing DOE regulations prior to certification. Despite NEI's opinion, the staff believes that the backfit process would have likely shown that these modifications were issues related to implementing the regulations and not backfit issues; however, the regulatory burden to show that each issue was related to implementing the regulations, instead of a backfit issue, would likely have been significant. Only after certification was completed, and experience was gained in implementing the Part 76 requirements, were backfit regulations implemented.

The above discussion clearly indicates that Part 70 regulations are much different than regulations to which backfit currently applies. As such, the staff continues to believe that backfit should only be considered after experience is gained in the implementation of the revisions to Part 70. Given the differences of opinion on this subject, the staff, however, plans to request public comment on its intent to defer the decision on a qualitative backfit provision in Part 70 in the Federal Register notice.

## **Issue 5: Reporting Requirements**

### **A. Contents of SECY-98-185**

In SECY-98-185, 10 CFR 70.74, and Appendix C, the staff proposed a graded approach for reporting licensee events. The rule specified three reporting classes and required specified events to be reported in 1, 4 and 24 hours from time of discovery. The approach was based on whether actual consequences had occurred, or whether a potential for such consequences existed. Serious events that had occurred were to be reported in 1 hour. Four-hour reporting was required for intermediate consequence events that had occurred; events that could potentially lead to consequences of concern; and events where controls could not be reestablished in 4 hours. If the controls could be reestablished in 4 hours, the event was to be reported within 24 hours.

### **B. Commission direction in SRM to SECY-98-185**

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

“The rule should contain criteria for protection against the occurrence of certain consequences and require reporting of certain significant events to NRC because of their potential to impact worker or public health and safety.”

### **C. Comments received during public interaction on draft rule language**

NEI comments expressed five concerns with the rule language contained in SECY-98-185, as follows: 1) reporting requirements for fuel cycle facilities are already adequately addressed in the existing rule -- a new rule chapter is unnecessary; 2) the new 1-hour reporting timeframe for certain events is too restrictive; 3) a licensee should not be required to report all personnel hazardous chemical exposures; 4) a licensee should not be required to conduct continuous radiological monitoring in the unrestricted or controlled areas of its facility; and 5) emergency reporting of “potential deviations” from safe operating practices or “potentially unsafe conditions” should not be required, since the language is too subjective. NEI provided additional comments on the staff’s revised draft proposed rule language. These comments were to eliminate duplication with other reporting requirements in Part 70 and to limit the reporting to two classes – serious events to be reported in 1 hour and significant events to be reported in 24 hours.

### **D. Staff response to SRM and disposition of comments**

In response to the Commission direction and the comments received, the staff revised the reporting requirements in 10 CFR 70.74 and Appendix A, to: 1) require reporting of certain significant events to NRC because of their potential to impact worker or public health and safety, consistent with the performance requirements in 10 CFR 70.61; 2) limit reporting to two classes (i.e., serious events to be reported in 1 hour and significant events to be reported in 24 hours); 3) clarify that continuous radiological monitoring in the unrestricted or controlled areas of its facility is not required; 4) clarify that only reporting of chemical exposures consistent with the performance requirements in 10 CFR 70.61 is required, not all chemical exposures; and 5) eliminate subjective language.

## **Issue 6: Performance Requirements Related to Chemical and Radiological Safety**

### **A. Contents of SECY-98-185**

In SECY-98-185, 10 CFR 70.60(b), the staff proposed inclusion of specific consequences against which licensees must provide adequate protection. These consequences, applicable to workers and members of the public, were categorized according to their level of severity (high and intermediate). Because accidents at fuel cycle facilities could result in human exposure to both radiological and chemical hazards, the staff proposed criteria that address both types of consequences. The staff-proposed rule in SECY-98-185 stated that the occurrence of any high-consequence event must be "highly unlikely," while the occurrence of any intermediate-consequence event must be "unlikely;" based on the draft Standard Review Plan definitions of the terms "highly unlikely" and "unlikely." This guidance is based on a combination of qualitative and quantitative indicators, but does not require a probabilistic risk assessment. The specific requirements are summarized in Table 6-1.

The chemical consequence criteria in SECY-98-185 were based on anticipated adverse health effects to humans from acute chemical exposures that were developed (or under development), by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances (Acute Exposure Guideline Limits (AEGLs)) and the American Industrial Hygiene Association (Emergency Response Planning Guidelines (ERPGs)). SECY-98-185 proposed two appendices for Part 70 that listed the applicable concentrations for the ERPG or AEGL standards. The chemical risk standards were not limited to chemicals produced from radioactive materials.

TABLE 6-1 Radiological and Chemical Consequence Criteria

Consequence	Worker		Public	
	Radiological	Chemical	Radiological	Chemical
High	> 1 Sv (100 rem) or Nuclear Criticality	> AEGL-3 (ERPG-3)	> 0.25 Sv (25 rem)	> AEGL-2 (ERPG-2)
Intermediate	< 1 Sv (100 rem)	< AEGL-3 (ERPG-3)	< 0.25 Sv (25 rem)	< AEGL-2 (ERPG-2)
	> 0.25 Sv (25 rem)	> AEGL-2 (ERPG-2)	> 0.05 Sv (5 rem)	> AEGL-1 (ERPG-1)

### **B. Commission Direction in SRM to SECY-98-185**

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

The rule should contain criteria for protection against the occurrence of certain consequences . . . because of their potential to impact worker or public health and safety. However, the Commission does not support the proposed rule with regard to chemical safety and consequence criteria. This issue warrants further discussion with affected agencies and industry to fully understand their respective authorities and the degree to which those authorities are implemented. The NRC should maintain its primary focus on its nuclear and

radiological safety mandate. Consideration should be given to clarifying the basis for use of chemical safety and chemical consequence criteria in the rule, particularly within the context of Memoranda of Understanding with OSHA and other government agencies.

### **C. Comments received during public interaction on draft rule language**

NEI provided several written comments on these issues during the period of public interaction on the staff's draft requirements. The U.S. Environmental Protection Agency and the Occupational Safety and Health Organization (OSHA) commented in response to a staff letter providing them the draft rule revisions. In addition, there were comments in the area of nuclear criticality posted on the World Wide Web discussion forum and in letters from both a member of the public and the American Nuclear Society. The wording for the performance requirements was a major topic of discussion at the three public meetings. The received written comments are described below.

In a November 4, 1998, letter, NEI commented that SECY-98-185 was deficient because it:

. . . will provide NRC regulatory jurisdiction over all 'chemical hazards resulting from the processing of licensed' radioactive material. The breadth of this jurisdiction exceeds that described in SECY-98-185 and in the 1988 NRC/OSHA Memorandum of Understanding (MOU). Proposed language in Part 70 can be construed to extend NRC regulation to any chemical hazard at a licensed fuel fabrication facility. NEI's principal objection to the draft Part 70 language is its failure to clearly separate the regulatory responsibilities of the NRC and OSHA as established in the MOU. As written, the draft rule will result in redundant, overlapping regulatory oversight that will not improve public or worker health and safety.

NEI recommended that NRC jurisdiction be limited, by the rule text, consistent with the MOU. Specifically, NRC would regulate: (1) Special Nuclear Material (SNM), (2) radioactive compounds (e.g.  $UF_6$ ), and (3) chemical compounds produced from radioactive materials during the processing of SNM (e.g. HF). NEI's November 4 letter also proposed several language changes including: a modification to the definition "hazardous chemicals"; addition of a definition for "hazardous chemicals produced from radioactive materials"; and deletion of the specific ERPG/AEGL values in Appendix B and C.

In a February 12, 1999, letter, NEI provided additional comments on the chemical safety risk standards, in response to staff revised rule language. NEI remarked, "the staff's proposed changes to the rule, for all intents and purposes, have resolved our concerns in the area of chemical safety. They constitute a major step forward in addressing our concerns that the rule be more "risk based" as opposed to "consequence' based."

In a response to an earlier NRC letter, OSHA commented on the staff's draft Part 70 revisions in a February 1, 1999 letter. OSHA noted that any regulation of chemical hazards or requirement to perform a hazards analysis is potentially preemptive of OSHA regulatory authority under the prevailing statute (i.e., the Occupational Safety and Health Act). The degree to which preemption would apply is largely dependent upon U.S. Circuit Court interpretations, which have exhibited regional variation. OSHA noted that this issue is independent of the division of responsibilities in the 1988 NRC-OSHA MOU, so, as the staff

understands OSHA's opinion, implementing the MOU in the Part 70 rule may not be appropriate. In a March 2, 1999, letter, NEI provided its opinion on OSHA's jurisdictional letter, stating NEI believes "that the Staff's suggested changes to the chemical hazards portions of the draft rule are appropriate and would not preempt any legitimate OSHA authority over non-radiological conditions at licensed Part 70 facilities. We again encourage you to incorporate the suggested modifications into the proposed rule." Also, at a February 25, 1999 meeting of NRC and OSHA staff, some clarifications and further information was provided at that meeting that resulted in some changes to the rule language to more clearly specify the scope of NRC involvement. However, these changes do not fully resolve the basic preemption issue. The problems identified with the rule are not unique, i.e., the preemption issue is generic and may already exist for any NRC-licensed facilities where there are requirements to analyze hazards. At the February 25 meeting, OSHA confirmed that the rule language is consistent with the October 21, 1988 MOU; indicated that they have no suggested changes to the MOU; and indicated that they are not opposed to the proposed rule.

The staff sent a similar letter to the U.S. Environmental Protection Agency (EPA) to solicit their views on the draft rule language. While OSHA has jurisdiction of workplace chemical safety, EPA regulates off-site (public) chemical safety. On May 24, 1999, EPA replied, noting that "EPA believes that the proposed revisions to NRC licensing regulations are consistent with the accident prevention portion of EPA's risk management program regulations and the general duty clause of the Clean Air Act." However, EPA requested that the rule contain an "explicit acknowledgment that [EPA] authority extends to applicable NRC-regulated facilities," that the preamble explain the relationship of the NRC and EPA rules similar to the explanation of OSHA rules (viz., the discussion on the NRC-OSHA MOU), and that NRC avoid any regulatory action that might inadvertently inhibit or restrict EPA's authority under 40 CFR Part 68.

In a December 17, 1998, letter, NEI commented on the nuclear criticality performance requirements. NEI recommended that the proposed revisions of 10 CFR 70 be clarified to reduce their ambiguity and the possibility of interpreting them to be 'consequence-based' rather than 'risk-based' regulations. While acknowledging that a nuclear criticality accident is an operating hazard whose risk must be adequately managed, NEI believed criticality should not be explicitly identified to be a "high consequence event" regardless of the resulting radiation doses. A letter from a member of the public, several submittals on the World Wide Web discussion forum, and by a December 1, 1998, letter from the Nuclear Criticality Safety Division of the American Nuclear Society advocated approaches that generally agreed with NEI's. In addition, NEI recommended that the rule permit industry to continue implementation of the double contingency principle as it has done without imposition of a probabilistic methodology, and Part 70 should be consistent with industry standards (American National Standards Institute, American Nuclear Society Standards Committee, Subcommittee ANS-8) that uphold the basic definition of the double contingency principle as adequate and sufficient.

#### **D. Staff response to SRM and disposition of comments**

The staff believes that the clarifications to the draft rule text related to chemical risks, criticality, and the use of risk-informed language in establishing the performance requirements, are consistent with the Commission's direction provided in the SRM and address NEI's and industry's concerns in this area.

The staff clarified the performance requirements section by:

- (1) consolidating the options that permit reducing the likelihood (prevention) or consequences (mitigation) in limiting the risk of accidents;
- (2) separating, for clarity, the information on applicability into §70.60, and the requirements for a three element safety program (process safety information, integrated safety analysis, and management measures) into §70.62;
- (3) providing a separate performance requirement for criticality using wording that matches the industry standards and stresses prevention of criticality, rather than including criticality within the subsection for high consequence events;
- (4) adopting qualitative language related to chemical risks, and permit quantitative standards (ERPG/AEGL) for them to be adopted or developed by the applicant specific to its processes;
- (5) defining “hazardous chemicals produced from licensed materials” such that the scope of the regulation is more clearly limited to the NRC’s areas of responsibility consistent with the 1988 NRC-OSHA MOU;
- (6) clearly stating the function of the ISA and the process for identifying items relied on for safety; and
- (7) clarifying the use of the term “controlled area” that defines the location of evaluation against the performance requirements for impacts to members of the public.

The revised rule language retains the basic consequence and probability scheme for limiting the risk of accidents. The numerical consequences were not changed from those in SECY-98-185, as shown above in Table 6-1; however, the reference to the ERPG and AEGL values was deleted from the rule in favor of qualitative language for chemical effects (the ERPG and AEGL techniques are listed in the standard review plan (SRP) as examples of acceptable approaches). Consequently, SECY-98-185 Appendices A and B, the chemical-by-chemical lists of ERPG and AEGL values, was deleted in agreement with the NEI comment. The SECY-98-185 version’s reliance on qualitative language related to the probability component of the risk (“highly unlikely” and “unlikely”) is retained. The applicant will be allowed to define his use of those terms, specific to that facility or process, in the application (i.e., in the ISA summary), and guidance is provided in the SRP.

The evaluation location for the accident standard for members of the public was specified in SECY-98-185 using the term “controlled site boundary” (meaning a physical barrier surrounding the facility). This became an issue during the public interaction period on the draft rule. Many commentators believed that NRC should incorporate the term, “controlled area” consistent with its use in 10 CFR Part 20. In response to this comment, the staff adopted the term “controlled area” in the performance requirements specified for the members of the public. The location at which compliance with the standard is evaluated is identified to be any point at or beyond the boundary of the “controlled area.”

Section 70.61(f) requires licensees to identify a controlled area consistent with the use of that term in Part 20, and provides clarification regarding the activities that may occur inside the controlled area. The function of this term is to delimit an area over which the licensee exercises control of activities to meet regulatory requirements. Control includes the power to exclude individuals, if necessary. The size of the controlled area is not specified in the regulation because it will be dependent upon the particular activities that are conducted at the site and their relationship to the licensed activities. Within the controlled area will be a restricted area (as defined in §20.1003) access to which is controlled by the licensee for purposes of radiation safety. Anyone not receiving an *occupational dose* (per Part 20) in the controlled area will be

subject to the dose limits for members of the public in 10 CFR 20.1301. However, the staff acknowledges that certain licensees may have ongoing activities on their site (i.e., within the controlled area) that are not related to the licensed activities. For example, a non-nuclear facility may be adjacent to the nuclear facility but both are within the controlled area (which may be defined similar to the site boundary). Protection of the individuals at the non-nuclear facility must consider that the nature of many potential accidents at a fuel cycle facility is such that they may not have substantive progression time during which to take action to exclude individuals from the controlled area. Therefore, for purposes of the ISA accident evaluation, the rule includes two options for these individuals. In the first option, the ISA evaluates the risk at their location (as opposed to any point at or beyond the controlled area boundary) and determines that it meets the performance requirements for members of the public. In the second option, performance requirements for workers can be applied to individuals in the controlled area if the provisions of Section 70.61(f)(2) are satisfied. These conditions ensure that the individuals are aware of the risks to them from the potential accidents at the nuclear facility and have received appropriate training and access to information (e.g., the ISA). This parallels and is consistent with the use of the term, "Exclusion area", by Parts 50 and 100, which state, "Activities unrelated to operation of the reactor may be permitted in an exclusion area under appropriate limitations, provided that no significant hazards to the public health and safety will result."

The staff believes that the ISA should not be used to evaluate compliance with the accident standards for individuals who make infrequent visits to the controlled area and restricted area (e.g., visitors). Use of the ISA to determine the risks to these individuals would need to consider second-order effects such as the probability of the individual being present at the time that the unlikely (or highly unlikely) accident occurred. This level of detail is unnecessary to accomplish the purpose of this rule (viz., to document and maintain the safety basis of the facility design and operations). Application of the Part 20 regulations provide adequate protection for these individuals. In addition, the provisions to protect workers during accidents (i.e., the performance requirements) provide a degree of protection to these individuals.

## **Issue 7: Standard Review Plan Modifications**

### **A. Contents of SECY-98-185**

A draft standard review plan (SRP) was included in SECY-98-185. The purpose of the draft standard review plan is to provide guidance to the staff reviewers in the Office of Nuclear Material Safety and Safeguards who perform safety and environmental impact reviews of applications to construct or modify and operate fuel cycle facilities. The SRP facilitates the quality, uniformity, stability, and predictability of staff reviews. The SRP also makes information about the licensing acceptance criteria widely available to interested members of the public and the regulated industry.

### **B. Commission Direction in SRM to SECY-98-185**

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

“The staff should critically review the Standard Review Plan in its entirety to ensure that, by providing specific acceptance criteria and program attributes to demonstrate compliance with the performance-based rule, it does not inadvertently prevent licensees or applicants from suggesting alternative means of demonstrating compliance.”

### **C. Comments received during public interaction on draft rule language**

In their November 25, 1998, letter to NRC, the Nuclear Energy Institute (NEI) provided the following:

NEI is concerned that new prescriptive, programmatic criteria introduced in the SRP without any specific basis in 10 CFR Part 70 will become de facto regulatory requirements. Although we recognize the SRP is only intended to be a staff guidance document to ensure consistency in license application reviews, the SRP acceptance criteria can over time become minimum standards ('lowest rung on the acceptance ladder'). The prescriptiveness of the draft SRP language is of particular concern. Though possibly not intended, it often appears to prejudge the need to implement new programs and practices before an Integrated Safety Analysis (ISA) establishes their need. In accordance with a risk-informed, performance-based regulatory approach, the SRP should reflect the philosophy that the licensee will propose appropriate programmatic activities based upon the risk significance identified in the ISA, and that the reviewer should expect a sound justification for each proposal from the licensee.

NEI provided other comments regarding quality assurance criteria, training and qualifications, fire safety, decommissioning, human-systems interface, organization and administration, emergency management, configuration management, maintenance, and criticality safety.

In letters dated December 17, 1998, and January 21, 1999, NEI provided criticality safety comments and an annotated mark-up of SRP Chapter 5, “Nuclear Criticality Safety.”

In a letter dated April 12, 1999, NEI provided comments on decommissioning and an annotated markup of Chapter 10, “Decommissioning”. In that letter, it states “...SRP Chapter 10 should be limited to a discussion of decommissioning funding plans, record retention requirements for new license applications, and waste/contamination plans.”

NEI also provided comments in the form of an annotated markup of SRP Chapter 6, "Chemical Process Safety," in a letter dated March 2, 1999.

#### **D. Staff response to SRM and disposition of comments**

The staff has stated from the outset, that the SRP is expected to be used during reviews as guidance. As stated on page 2 of the June 1998 draft SRP, "The 'Acceptance Criteria' delineated in this SRP are intended to communicate the underlying objectives but not to represent the only means of satisfying that objective. If approaches different from the SRP are chosen, the applicant should identify the portions of its application that differ from the design approaches and acceptance criteria of the SRP and evaluate how the proposed alternatives provide an acceptable method of complying with the Commission's regulations." This approach is not different from the approach presented in NEI's November 25, 1998, comments stated in C above. The intent is that the acceptance criteria is only one specific approach, which if followed, is intended ensure acceptance by the reviewer in most, if not all, situations. However, because the proposed regulations allow a graded approach based upon the significance of the process being evaluated, the applicant may propose approaches different from that proposed in the acceptance criteria; these differing approaches may result in smaller programs or no program to meet the category under review. The applicant is only required to identify that they are using a different approach from that presented in the SRP and based upon the applicant's evaluation, provide an explanation for the alternative approach used. This is consistent with NEI's statement "that the reviewer should expect a sound justification for each proposal from the licensee."

NEI has mentioned some concern that NRC's statements in the introduction of the SRP may be overlooked in the future and acceptance criteria may still become "de facto" requirements. As such, the acceptance criteria of each section will include a statement "the reviewed item should be considered acceptable if the applicant has met the following acceptance criteria or has identified and justified an alternative in the application."

The staff has revised the SRP to be consistent with the rule language and has incorporated many of the comments received on the SRP, especially in the chemical safety and criticality safety chapters.

## **Issue 8: Use of ISA Methodologies in the Licensing of New Technologies**

### **A. Contents of SECY-98-185**

In SECY-98-185, the ISA to be performed was described as a systematic analysis to identify plant and external hazards and their potential for initiating accidents; the potential accident sequences and their likelihood and consequences; and the items that are relied on for safety. Specific ISA methodologies that could be used were described in NUREG-1513, "Integrated Safety Analysis" guidance document. Flexibility was permitted in the ISA methodology chosen so that it would be appropriate to the process and technology being analyzed.

### **B. Commission Direction in SRM to SECY-98-185**

The Commission, in the SRM to SECY-98-185, directed the staff as follows:

"Also, in soliciting public comments, the staff should request input on how applicable ISA methodologies should be employed in the licensing of new technologies for use within new or existing facilities."

### **C. Comments received during public interaction on draft rule language**

No comments were specifically received addressing this issue, nor were there any concerns expressed on the application of ISA methodologies to new technologies..

### **D. Staff response to SRM and disposition of comments**

The ISA methodology described in this rule and SRP have not changed from that described in SECY-98-185. The ISA guidance document (NUREG-1513) also has not changed. The staff continues to believe that sufficient flexibility is permitted in the ISA methodology chosen to be able to accommodate a wide range of technologies. However, to better address the Commission concern, the draft Federal Register notice associated with this proposed rule specifically requests comments on this matter.